

August 13, 2020

**Submission of the
HEALTH PRODUCTS STEWARDSHIP ASSOCIATION
on
ERO Number 019-1760**

A. THE GOVERNMENT’S PROPOSAL

The Ontario government is proposing regulatory changes that are intended to improve the speed, and reduce the complexity and costs of reporting hazardous waste movements in Ontario and transferring operational control for a new digital reporting service from the Ministry of the Environment, Conservation and Parks (“MECP”) to the Resource Productivity & Recovery Authority (“RPRA”).

As the operator of multiple stewardship programs across Canada for waste pharmaceuticals and ‘medical sharps’, the Health Products Stewardship Association (“HPSA”) welcomes the opportunity to comment on the proposed changes to the Hazardous Waste Program outlined in ERO Number 109-1760, a discussion paper on Modernizing Hazardous Waste Reporting in Ontario (the “Discussion Paper”).

HPSA focus in this submission is to comment on those proposed changes which might have an adverse impact on the successful continuation of its current stewardship programs in Ontario.

B. ABOUT THE HPSA

1. HPSA is an industry funded, not-for-profit federal corporation which is the Industry Funding Organization in Ontario that administers stewardship for the collection and management of unused and expired post-consumer pharmaceuticals and medical sharps from collection sites (retail pharmacies) in Ontario and across Canada.

2. HPSA’s *Ontario Medications Return Program* (OMRP) covers the costs associated with the responsible disposal of health products returned by the public. The products covered under this program are:

- All prescription drugs,
- Over-the-counter Medications, and
- Natural Health Products in oral dosage form.



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3. HPSA's *Ontario Sharps Collection Program* (OSCP) is a stewardship program that promotes the safe and easy disposal of sharps from the public so that they aren't disposed of in the garbage. The definition for sharps includes; infusion sets, safety pens and syringes with needles attached, lancets, needle tips, needles, pens, pen needles, pre-filled cartridges and pre-filled syringes.

C. COMMENTS AND OBSERVATIONS

1. HPSA supports all reasonable laws and other measures to ensure that hazardous wastes are appropriately and safely managed, while maintaining the ready and convenient access of Ontario residents to return pharmaceutical products and medical sharps to their local retail pharmacies. The 'return to point of sale' stewardship model provides the necessary convenience to Ontario residents. The existing regulatory framework for retail pharmacies in Ontario results in a high level of safety and security for the receipt, handling and storage of pharmaceuticals and medical sharps.

2. HPSA's stewardship programs feature the mandatory use by participating pharmacies of specially designed, constructed, colored and labelled containers for returned household pharmaceuticals and separately designed, constructed, colored and labelled containers for medical sharps.

3. Improper disposal of medications and medical sharps is potentially harmful to people, animals and the environment. HPSA submits that the requirements governing the stewardship of household pharmaceuticals and medical sharps through the *Environmental Protection Act, Ontario Regulation 347* and *Ontario Regulation 298/12* has ensured that all received materials are handled, stored, transported and disposed in a manner that protects the environment and human health. The exemptions in section 5 of *Ontario Regulation 298/12* removes the onerous administrative burdens and costs that would otherwise prevent the participation of a high percentage of Ontario's retail pharmacies in HPSA's stewardship programs.

4. Once collected from participating pharmacies and consolidated by one or more licensed hazardous waste contractors, all movements and disposal operations for the pharmaceuticals and medical sharps are carried out in full compliance with Ontario laws, and utilize Ontario's existing Hazardous Waste Information Network as required.



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5. Page 6 of the Discussion Paper lists four steps that constitute the Hazardous Waste Program:

Step 1 Registration and Payment

Step 2 Approvals

Step 3 Compliance & Enforcement; and

Step 4 Tracking & Report

6. Regarding Step 1, Registration and Payment – in the context of HPSA’s stewardship programs, individual participating pharmacies should not be required to register as a hazardous waste generator, nor should participating pharmacies be required to pay a fee to the MECP, RPRA or other regulatory authority.

7. Regarding Step 2, Approvals – the MECP has already approved the pharmaceuticals and medical sharps stewardship programs and has received annual reports from HPSA for almost a decade. Individual participating pharmacies should not be required to obtain a separate approval from the MECP, RPRA or other regulatory authority to participate in the HPSA stewardship programs.

8. Regarding Step 3, Compliance and Enforcement – HPSA, its stewardship program contractors who provide collection, disposal and other services, and participating collection sites (retail pharmacies) must comply with their respective obligations in the approved stewardship programs and other applicable laws. HPSA accepts that compliance is vital to a safe environment and the health and safety of Ontario workers and residents, and that the MECP, RPRA or other regulatory authorities can and should undertake compliance monitoring, and where necessary, enforcement measures.

9. Regarding Step 4, Tracking and Reporting - tracking and reporting are important compliance tools. HPSA has and will continue to generate tracking data and reports to the MECP, RPRA or other regulatory authority as required by applicable laws and/or the terms and conditions of the approved stewardship programs.

10. HPSA’s service providers such as Stericycle Canada utilize the current Hazardous Waste Information Network for the movement and disposal of pharmaceuticals and medical sharps with HPSA’s stewardship programs, after the relevant materials have been collected from the participating pharmacies. HPSA submits that the current level of reporting and tracking for the pharmaceuticals and medical sharps programs provides sufficient and timely information to allow the MECP, RPRA or any other regulatory authority to monitor performance and take enforcement actions if and when necessary.



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11. A statement appears on pages 8 and 9 of the Discussion Paper that the new digital reporting service will save businesses time and money. HPSA expects that this statement means that any existing fees for generator registration and/or manifests will not increase and that no new fees will be introduced.
12. Statements appear throughout the Discussion Paper that the new digital reporting service for manifests will replace the existing paper based manifest program. HPSA supports any efforts by the MECP and/or RPRA to replace the existing paper based manifest system with a user friendly digital manifest system.
13. The description of proposed changes on pages 10 and 13 of the Discussion Paper indicates that a new regulation will be passed under RRCEA to “carry over a fee exemptions framework which will maintain the current fee exemptions.” It is vital to HPSA’s stewardship programs that exemptions under **Ontario Regulation 298/12** continue to apply to HPSA’s stewardship programs.
14. A statement appears on page 12 of the Discussion Paper that through recent changes to RRCEA, RPRA will have the ability to set and collect fees. Should the MECP proceed with the proposed changes, there needs to be an additional exemption in **Ontario Regulation 298/12** to provide an appropriate fee exemption for HPSA and the HPSA participating pharmacies.
15. A statement appears on page 13 of the Discussion Paper that the Hazardous Waste program will continue to operate as a full cost recovery program. As long as the current structure in **Ontario Regulation 298/12** is retained, including the exemptions in section 5, there will be no costs to the Hazardous Waste program, and therefore no need for cost recovery from the HPSA or its participating pharmacies. HPSA’s service contractors will continue their participation in the Hazardous Waste program for all handling and disposal of hazardous wastes after the collection of pharmaceuticals and medical sharps from participating pharmacies.
16. A statement appears on page 14 of the Discussion Paper regarding the tracking of locations and other business information. HPSA currently provides annual reports to the MECP on the identity of participating pharmacies and the quantity of pharmaceuticals and medical sharps collected and disposed. HPSA opposes any new registration or reporting requirements for participating pharmacies. HPSA will continue to report such relevant information on an annual basis, whether it is directly to the MECP or the RPRA or other regulatory authority responsible for Ontario Regulation 298/12.



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17. With respect to question #1 on page 14 of the Discussion Paper, HPSA provides consolidated reports on the collection, movement and disposal of pharmaceuticals and medical sharps on behalf of all pharmacies and other participants in HPSA's stewardship programs. HPSA should be allowed to continue to provide that function on behalf of all pharmacies and other participants in the stewardship programs.
18. With respect questions #2 on page 14 of the Discussion Paper, any person required to maintain records regarding the collection, handling or disposal of hazardous wastes should not be required to maintain paper records, provided that they have recorded and retained the relevant information electronically.
19. With respect questions #3 on page 14 of the Discussion Paper, HPSA submits that the Spills Action Centre should continue its existing role in the unlikely event that there is a spill of hazardous waste involving its stewardship programs.
20. Statements appears on pages 16 and 17 of the Discussion Paper regarding the reporting of short term storage of hazardous wastes. Under HPSA's stewardship programs, participating pharmacies must engage in short term storage of pharmaceuticals and/or medical sharps until a sufficient quantity is collected to merit pickup and consolidation by HPSA's contractors. Participating pharmacies are not currently required to register or report their short term storage of materials received through the HPSA stewardship program. This exemption should be continued.
21. With respect questions #2 on page 17 of the Discussion Paper, HPSA submits that HPSA and its licensed service contractors should have access to online data for a period of up to three (3) years from the time that the data is created. The rationale for this time frame is that in the unlikely event that a specific record becomes the subject of a regulatory investigation, charges or a civil dispute, such proceedings must be commenced within two years of the relevant events. A three-year access window would allow the relevant parties to access information relevant in the event of an investigation, charges, or civil claims.
22. With respect question #7 on page 18 of the Discussion Paper, flexibility in the reporting units for quantities generated and transported would be a positive and welcome step, particularly if HPSA can report on the number of HPSA's standardized collection containers (HPSA would provide dimensions of the containers and other information that



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may be reasonably necessary to determine an approximate quantity of the materials received, transported and disposed).

23. With respect question #1 on page 19 of the Discussion Paper, provided that the reporting structure and regulatory exemptions which are currently a part of **Ontario Regulation 298/12** remain in place, a six-month transition period from the current manifest system to a new digital system would be adequate.

D. HPSA RECOMMENDATIONS

1. In light of HPSA's successful operation and growth of the pharmaceuticals stewardship program and the medical sharps stewardship program over the past decade, HPSA recommends that there should be no changes to **Ontario Regulation 298/12**.
2. In the event that the Ontario government is contemplating a change from the MECP to RPRA for HPSA's stewardship programs, then all of the exemptions set out in section 5 of **Ontario Regulation 298/12** should be carried forward into any replacement or amendment of **Ontario Regulation 298/12**.
3. There should be no increase in any administrative burdens and/or costs to participating pharmacies in HPSA's stewardship programs. Any increase in administrative burdens for a waste generator registration, temporary storage report or movement document will most likely result in an immediate and substantial decrease in the number of participating pharmacies. No Canadian Province requires any separate waste generator registration, interim storage reports or movement documents from participating pharmacies in HPSA's stewardship programs in other parts of Canada. All of the data that the MECP, RPRA and their counterparts in other Canadian Provinces currently require, is provided by HPSA through its annual reports.



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E. CONCLUSIONS

1. HPSA submits that the proposed transition from the current mix of digital and paper manifests to a new simpler digital manifest system is a positive development, however if the MECP is contemplating any amendments to Ontario Regulation 298/12, then such changes should be the subject of a separate and independent consultation from ERO Instrument 019-1760.
2. HPSA remains at all times willing to work with MECP and other stakeholders to improve the pharmaceuticals and medical sharps stewardship programs.

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